

Glycotest is developing a new Test for Detecting Early Stage Liver Cancer with the revolutionary approach of using Glycoproteins as Biomarkers



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CEOCFO: Mr. Cohen, what is the concept behind Glycotest?

Mr. Cohen: Glycotest is a private, liver disease diagnostic company. Our mission is to detect early stage liver cancer. Currently, the diagnostic products on the market for detecting liver cancer catch it too late to qualify patients for curable therapy. Current tests are not very good at diagnosing the disease early enough to do something about it. Therefore, unfortunately, most patients that are diagnosed with liver cancer are diagnosed when the cancer is advanced, and they will most likely get some form of chemo- therapy. Unfortunately, for liver cancer the outcomes are not very good for patients getting chemo- therapy. However, if it is caught early then patients can have surgery or ablation therapy and in many cases the cancer is curable.

CEOCFO: What is the Glycotest approach?

Mr. Cohen: Regarding our approach, our innovators were researching methods to detect early-stage hepatocellular carcinoma or the most common form of liver cancer. This led to discovering glycoproteins that could be used as biomarkers. What we actually measure is a monosaccharide sugar (core fucose) that gets deposited on these glycoproteins or biomarkers and we call that Fucosylation. For those patients that have these relatively high fucosylated glycoproteins, it means that there is a high likelihood that they have HCC or liver cancer. Therefore, we have three proprietary biomarkers and there are three other commonly available blood tests that we use in our HCC Panel.

We combine the results of those tests in our HCC Panel, along with the patient's age and gender and this information gets input into an equation or an algorithm. The algorithm then produces an HCC likelihood score. If it is over a cutoff it is very likely that that patient has liver cancer and their physician, when they get that score, would then refer them to a confirmatory test, like an MRI or a CAT scan.

CEOCFO: Is the score clear cut? Is there a subjective part to each of the components? What is reviewed?

Mr. Cohen: The score is very clear and binary. Either the patient is above the cutoff or below the cutoff. As I said, this is not a confirmatory test, but it is for people that have some chronic liver disease and are at a higher risk today for hepatocellular carcinoma. For example, if anyone has had hepatitis of any type or if they have cirrhosis, they are at elevated risk for liver cancer. Those patients typically are involved in a surveillance program to detect cancer early so it can be treated appropriately. The AASLD (American Association for the Study of Liver Disease recommends these patients see their physician and get tested approximately every 6 months.

Currently, the test is either an abdominal ultrasound or ultrasound along with a blood test named AFP. However, as I mentioned, these tests do not work very well in detecting early-stage cancer. They do detect cancer, but unfortunately, when the tumor is too large to provide curative therapy. Therefore, our test is designed to pick up the cancer at an early-stage. By catching the liver cancer early enough, the patient could qualify for a liver resection, where the tumor is surgically removed and then the liver regenerates. There are also other treatments, like a radio-frequency ablation, where again, the tumor is basically eliminated, and the patient has good outcomes with these procedures.

CEOFCO: *Where are you in the process?*

Mr. Cohen: We have already done three clinical trials with very good results, significantly better than those methods that exist today. We are doing, what I would consider a pivotal clinical trial right now. We started enrolling patients at the end of May. It will take about a year to get a sufficient number of patients. We are going to have about five hundred patients in this study. We are optimistic and hoping that the results will support the previous clinical studies that have been completed. We would expect that the principal Investigators (PIs) of the study will submit to a peer reviewed journal and get it published.

We are going to introduce the test as a lab developed test (LDT), which if you are not familiar with, lab developed tests are currently regulated by CMS, which is the Centers for Medicare and Medicaid, and we will offer the services of a CLIA lab. CLIA is a certain regulatory designation. We will have our sales force call on hepatologists to make them aware of the test. Obviously, we will make physicians aware of the publication, assuming that it gets published and we will be off and running. We have other tests in our pipeline beyond the HCC Panel that we have discussed. HCC stands for Hepatocellular Carcinoma, which is the primary form of liver cancer.

“Our mission is to detect early-stage liver cancer” - Larry Cohen

CEOFCO: *Are you testing blood?*

Mr. Cohen: Yes. It is a small blood sample that physicians would draw in their office or the patient will go to a lab to have their blood drawn and then it will be sent to our CLIA lab.

CEOFCO: *What has been the response from the medical community that might be aware of what you are doing?*

Mr. Cohen: So far it has been outstanding! As I said, we have data from three clinical studies. We have shown key opinion leaders for liver disease and HCC the results and they have been impressed with the HCC Panel performance vs. currently available tests.

We are detecting patients with early stage disease that other tests have missed and we believe we can really save people's lives. Liver cancer, or hepatocellular carcinoma, is on the rise here in the United States. It is the fastest growing type of cancer that causes death.

CEOFCO: *Is that because we have better treatments or preventions for the other cancers or as people are getting older are more people susceptible to liver cancer?*

Mr. Cohen: It is a little bit of both. There are some chronic liver diseases such as fatty liver disease and NASH that put patients at a higher risk for HCC, and unfortunately the prevalence of these diseases are growing at a rapid pace. Those patients can progress to get cirrhosis and ultimately hepatitis and those are driving the prevalence of liver cancer. What happens is that your liver gets stiff (fibrosis), and it losses functionality. Then you become much more susceptible to hepatocellular carcinoma. You will not necessarily get liver cancer, but you are definitely more susceptible to get it.

As I mentioned earlier, The American Society for the Study of Liver Disease recommends that people that have had any type of hepatitis or have cirrhosis, should be in a surveillance program. A surveillance program means that you see your physician approximately every six months, and they will examine you and do the appropriate tests for HCC. However, as I said, what is available right now misses many, many early-stage cases, because the tests are just not sensitive enough.

CEOFCO: *How much data do you need?*

Mr. Cohen: There is no magic number, but we have had a statistician review our protocol for the study that we just started and we believe that we have targeted the appropriate size. We are recruiting five hundred patients through twelve academic medical centers, so roughly forty to fifty per center. As I said, that will probably take about a year, because it is not just getting enough patients to donate their blood for the clinical trial. We need a certain number of positive cases and a certain number of negative cases, to make it statistically accurate.

CEO CFO: *Is it easy to get participation in this type of study since it is a one and done commitment?*

Mr. Cohen: Yes, typically it is. If you go to the right medical centers that see these types of patients and the right physicians, hepatologists or other specialties that see these patients. Therefore, you can get patients enrolled and we are doing that. However, as I said, you need large numbers because you have to get enough of what we call “cases,” those are people with cancer and “controls,” those are people that have cirrhosis or hepatitis or have had hepatitis, but they do not have cancer. That is really what we are trying to demonstrate in the study; that we can differentiate between cirrhosis patients and cancer patients. That is really the magic, so to speak.

CEO CFO: *Are there other tests in the works?*

Mr. Cohen: Yes. We have a test in the pipeline for fibrosis. Fibrosis is a stiffening of the liver. It is caused by many different things. In some cases it could be caused by abuse of alcohol but it also can be caused by hepatitis and other liver diseases. Physicians want to understand what stage of fibrosis a patient is in. It is not binary; either you have fibrosis or you do not, it is more about what stage of fibrosis the patient is in so that the patient can be given the appropriate treatment.

There are drugs that are in trials now that are being tested to see which patients with fibrosis at different stages could benefit from a particular drug. Therefore, even to know how to treat the patient, the physician would like to know what stage of fibrosis the patient is in. That is one test that is in the works. Then we have another test for a different type of liver cancer called cholangiocarcinoma. It is more rare than primary liver cancer, hepatocellular carcinoma, but currently there aren't any effective tests for it. Those are the two tests behind the HCC panel and that will come out in the coming years.

CEO CFO: *You had a funding a few months back. How far will that take you?*

Mr. Cohen: The funding was from a company named Fosun Pharma. It is a Chinese company. In China, liver disease is a huge problem, because there many millions of patients that have had hepatitis, that have been exposed to it, so they are at higher risk for liver disease and HCC. They have committed to ten million dollars in investment and that will take us through our product launch, which will be a little more than a year from now, in the third quarter of 2020. We will raise another round of financing mid next year to ensure that we have sufficient funds to launch a very strong marketing program.

CEO CFO: *So far through the development, what have you learned that may have surprised you?*

Mr. Cohen: There are surprises every day in this kind of business! However, one thing that we were worried about is will the test work for genetic differences, such as with Chinese people, Japanese people, Hispanic people or Caucasian people. So far, in all of the trials we have done, it does. Therefore, that was a good surprise in that we did not have to make modifications for different patient populations.

This trial that we are doing now, and trials that will occur as well in China, will hopefully validate that, but with the data we currently have, it works on everybody. The other thing is that while there are companies out there that are trying to develop tests for early detection of liver cancer, I think we are in the lead and if we stay on schedule we will be the first to market with this new type of test that detects early stage cancer.

CEO CFO: *There are so many new companies or new ideas, new concepts to look at. Why is Glycotest so important?*

Mr. Cohen: The bottom line is that we believe we could save lives and obviously, that is very important, especially because if the cancer is detected early, surgery can be used to save patient's lives. That is number one. Number two, with the growing population of fatty liver disease and NASH, which stands for Non-Alcoholic steatohepatitis, it starts becoming much more important to find liver cancer in these patients early so that they can be cured.

